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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,935	01/15/2002	Yuqiu Jiang	210121.527C1	4541

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EXAMINER	
SPIEGLER, ALEXANDER H	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,935	JIANG ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

    1. Claims 1, 3, 4, 8, 11 (in part) and 15, drawn to nucleic acids, vectors, host cells and kits and compositions comprising said nucleic acids, classified in class 536, subclass 23.1 and class 435, subclasses 320.1 and 325, for example.

    2. Claims 2, 7 and 11 (in part), drawn to polypeptides, fusion proteins and compositions comprising said polypeptides and fusion proteins, classified in class 530, subclass 350, for example.

    3. Claims 5, 11 (in part) and 16, drawn to antibodies and kits and compositions comprising said antibodies, classified in class 530, subclass 387.1, for example.

    4. Claim 6, drawn to a method of detecting the presence of cancer using a polypeptide, classified in class 435, subclass 4, for example.

    5. Claim 9 (in part), drawn to a method of stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with a polypeptide, classified in class 435, subclass 4, for example.

    6. Claim 9 (in part), drawn to a method of stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with a nucleic acid, classified in class 435, subclass 6, for example.

    7. Claim 9 (in part), drawn to a method of stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with an antigen-presenting cell, classified in class 435, subclass 7.1, for example.

8. Claims 10 and 11 (in part), drawn to an isolated T cell population and a composition comprising said T cell population, classified in class 435, subclass 333, for example.

9. Claim 11 (in part), drawn to a composition comprising an antigen presenting cell that express a polypeptide, classified in class 435, subclass 326, for example.

10. Claim 12 (in part), drawn to a method of stimulating an immune response in a patient comprising administrating a polypeptide or fusion protein, classified in class 435, subclass 4, for example.

11. Claim 12 (in part), drawn to a method of stimulating an immune response in a patient comprising administrating a nucleic acid, classified in class 435, subclass 6, for example.

12. Claim 12 (in part), drawn to a method of stimulating an immune response in a patient comprising administrating an antibody, classified in class 435, subclass 7.1, for example.

13. Claim 12 (in part), drawn to a method of stimulating an immune response in a patient comprising administrating a T cell population, classified in class 435, subclass 7.21, for example.

14. Claim 12 (in part), drawn to a method of stimulating an immune response in a patient comprising administrating an antigen presenting cell, classified in class 435, subclass 7.23, for example.

15. Claim 13 (in part), drawn to a method of treating cancer comprising administrating a polypeptide or fusion protein, classified in class 514, subclass 2, for example.

16. Claim 13 (in part), drawn to a method of treating cancer comprising administrating a nucleic acid, classified in class 514, subclass 44, for example.

17. Claim 13 (in part), drawn to a method of treating cancer comprising administrating an antibody, classified in class 514, subclass 1, for example.

18. Claim 13 (in part), drawn to a method of treating cancer comprising administrating a T cell population, classified in class 514, subclass 1, for example.

19. Claim 13 (in part), drawn to a method of treating colon cancer comprising administrating an antigen presenting cell, classified in class 514, subclass 2, for example.

20. Claim 14, drawn to a method for determining the presence of cancer using a nucleic acid, classified in class 435, subclass 6, for example.

21. Claim 17 (in part), drawn to a method for the treatment of colon cancer in a patient by incubating CD4+ and/or CD8+ T cells from a patient with a polypeptide, classified in class 514, subclass 2, for example.

22. Claim 17 (in part), drawn to a method for the treatment of colon cancer in a patient by incubating CD4+ and/or CD8+ T cells from a patient with a nucleic acid, classified in class 514, subclass 44, for example.

23. Claim 17 (in part), drawn to a method for the treatment of colon cancer in a patient by incubating CD4+ and/or CD8+ T cells from a patient with an antibody, classified in class 514, subclass 1, for example.

Further Restriction

2. The claims of Group 1-23 are drawn to a multitude of nucleic acids, polypeptides, antibodies thereto and methods which use these compounds. Each of the different nucleic acids, polypeptides, antibodies and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups 1-23, Applicant is additionally required to elect a **single** nucleic acid, polypeptide, or antibody (e.g., Applicants must elect one SEQ ID NO). For example, Applicants could elect Group 1, and SEQ ID NO: 1 or Group 6 and SEQ ID NO: 1. This requirement is not to be construed as a requirement for an election of species, since each of the compounds is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

3. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups 1-3 and 8-9 are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group 1 is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group 2 is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group 3 is also composed of

amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. T-cells and antigen presenting cells comprise cytoplasm and other cellular matter not found in nucleic acids, polypeptides and antibodies, and furthermore, T cells and antigen presenting cells are distinct from one another as a T cells have very specific cellular matter as compared to a broadly defined antigen presenting cell. Furthermore, the products of Groups 1-3, can be used in materially different processes, for example, the DNA of Group 1 can be used in hybridization assays, the antibody of Group 3 can be used in immunoassay, the polypeptide of Group 2 can be used to make fusion protein with an enzymatic function. T cells can be used in assays for determining immune response, whereas antigen presenting cells can be used in treatment assays Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups 1-3 and 8-9 are patentably distinct from each other.

B) Inventions 1 and (4-5, 7, 10, 12-15, 17-19, 22 and 24) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the nucleic acids of Group 1 are not required for the methods of Groups 4-5, 7, 10, 12-15, 17-19, 22 and 24.

C) Inventions 1 and (6, 11, 16, 20 and 22) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group 1 could be used in any of the methods of 6, 11, 16, 20 and 22, or in an entirely different manner, such as in synthesizing proteins.

D) Inventions 2 and (6-7, 11-14, 16-20 and 22-23) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptides of Group 2 are not required for the methods of Groups 6-7, 11-14, 16-20 and 22-23.

E) Inventions 2 and (4-5, 10, 15 and 21) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group 2 could be used in any of the methods of 4-5, 10, 15 and 21, or in an entirely different manner, such as in a purification reaction or in making antibodies.

F) Inventions 3 and (4-7, 10, 11, 13-16 and 18-22) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies of Group 3 are not required for the methods of Groups 4-7, 10, 11, 13-16 and 18-22.

G) Inventions 3 and (12, 17 and 23) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group 3 could be used in any of the methods of 12, 17 and 23, or in an entirely different manner, such as in the production of anti-idiotypic antibodies

H) Inventions 8 and (4-7, 10-12, 14-17 and 19-23) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the T cell population of Group 8 is not required for the methods of Groups 4-7, 10-12, 14-17 and 19-23.

I) Inventions 8 and (13 and 18) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the T cell population of Group 8 could be used in any of the methods of 13 and 18, or in an entirely different manner, such as in a immune response assay.

J) Inventions 9 and (4-6, 10-13, 15-18 and 20-23) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antigen presenting cells of Group 9 are not required for the methods of Groups 4-6, 10-13, 15-18 and 20-23.

K) Inventions 9 and (7, 14 and 19) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antigen presenting cells of Group 9 could be used in any of the methods of 7, 14 and 19, or in an entirely different manner, such as in expression assays.

L) Inventions 4-7 and 10-23 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are directed to methods having different method steps, starting materials, and goals.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions 1-23 require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
January 26, 2004

CARLA J. MYERS
PRIMARY EXAMINER